

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property  
Organization  
International Bureau



(43) International Publication Date  
19 May 2005 (19.05.2005)

PCT

(10) International Publication Number  
**WO 2005/044834 A1**

(51) International Patent Classification<sup>7</sup>: **C07H 17/00,**  
A61K 31/7052

(74) Agent: **GRUBB, Philip**; Novartis AG, Corporate Intellectual Property, CH-4002 Basel (CH).

(21) International Application Number:  
PCT/EP2004/012566

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(22) International Filing Date:  
5 November 2004 (05.11.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:  
10/702,690 6 November 2003 (06.11.2003) US

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(71) Applicant (*for all designated States except US*): **SANDOZ AG** [CH/CH]; Lichtstrasse 35, CH-4056 Basel (CH).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): **SADATREZAEI, Mohsen** [IR/US]; 4124 Primrose Drive, Allentown, PA 18104 (US). **DAVILA, Pablo** [US/US]; 130 Woods Road, East Windsor, NJ 08520 (US). **BARBERA, Gary** [US/US]; 17 Huntington Circle Drive, Medford, NJ 08055 (US).

Published:

— with international search report

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: A STABILIZED AZITHROMYCIN COMPOSITION

(57) Abstract: A method for preparing a stabilized azithromycin composition comprising mixing azithromycin monohydrate and water to form a stabilized azithromycin composition having a water content from about 5 to about 15 weight percent, based on the total weight of the composition, wherein said method is conducted within a humidity range of 20-99% relative humidity. The present inventors have unexpectedly determined that a certain amount of water is necessary to stabilize a pharmaceutical composition comprising azithromycin monohydrate. In addition, the stabilized azithromycin monohydrate compositions do not require an antioxidant.

WO 2005/044834 A1